European Medicines Agency
Evaluation of Medicines for Human Use

London, 7 September 2007
Doc. Ref. EMEA/HMPC/283166/2007

COMMITTEE ON HERBAL MEDICINAL PRODUCTS (HMPC)

DRAFT

COMMUNITY HERBAL MONOGRAPH ON *SAMBUCUS NIGRA* L., FLOS

DISCUSSION IN WORKING PARTY ON COMMUNITY MONOGRAPHS AND COMMUNITY LIST (MLWP)	July 2007 September 2007
ADOPTION BY HMPC FOR RELEASE FOR CONSULTATION	7 September 2007
END OF CONSULTATION (DEADLINE FOR COMMENTS)	15 December 2007
REDISCUSSION IN WORKING PARTY ON COMMUNITY MONOGRAPHS AND COMMUNITY LIST (MLWP)	
ADOPTION BY HMPC	

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KEYWORDS	Herbal medicinal products; HMPC; Community herbal monographs; traditional use; *Sambucus nigra* L.; Sambuci flos; elder flower

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COMMUNITY HERBAL MONOGRAPH ON *SAMBUCUS NIGRA* L., FLOS

1. NAME OF THE MEDICINAL PRODUCT

To be specified for the individual finished product.

2. QUALITATIVE AND QUANTITATIVE COMPOSITION[1, 2]

Well-established use	Traditional use
With regard to the marketing authorisation application of Article 10(a) of Directive 2001/83/EC as amended	With regard to the registration application of Article 16d(1) of Directive 2001/83/EC as amended *Sambucus nigra* L., flos (elder flower) i) Herbal substance - Dried flower ii) Herbal preparations A) Liquid extract 1:1 DER in 25 % V/V ethanol B) Liquid extract 1:1 DER in 70% V/V ethanol C) Tincture 1:5 DER in 25 % V/V ethanol

3. PHARMACEUTICAL FORM

Well-established use	Traditional use
	Herbal preparations in liquid dosage forms for oral use. The pharmaceutical form should be described by the European Pharmacopoeia full standard term.

[1] The material complies with the Eur. Ph. monograph (ref. 01/2005:1217)
[2] The declaration of the active substance(s) for an individual finished product should be in accordance with relevant herbal quality guidance.

4. CLINICAL PARTICULARS

4.1. Therapeutic indications

Well-established use	Traditional use
	Herbal medicinal product traditionally used for the relief of early symptoms of common cold. The product is a traditional herbal medicinal product for use in specified indications exclusively based upon long-standing use.

4.2. Posology and method of administration

Well-established use	Traditional use
	Posology *Adolescents over 12 years of age, adults, elderly* Herbal substance for tea preparation:2-5 g: three times daily A) Liquid extract 1:1 DER in 25 % V/V ethanol: 3-5 ml three times daily B) Liquid extract 1:1 DER in 70% V/V ethanol: 5 ml three times daily C) Tincture 1:5 DER in 25 % V/V ethanol: 10-25 ml three times daily The use is not recommended in children under 12 years of age (see section 4.4 Special warnings and precautions for use). **Duration of use** Not to be taken for more than 1 week.. If the symptoms persist during the use of the medicinal product, a doctor or a qualified health care practitioner should be consulted. **Method of administration** Oral use.

4.3. Contraindications

Well-established use	Traditional use
	Hypersensitivity to the active substance.

4.4. Special warnings and precautions for use

Well-established use	Traditional use
	The use is not recommended in children under 12 years of age due to lack of adequate data. When dyspnoea, fever or purulent sputum occurs, a doctor or a qualified health care practitioner should be consulted. For tinctures and extracts containing ethanol, the appropriate labelling for ethanol, taken from the 'Guideline on excipients in the label and package leaflet of medicinal products for human use', must be included.

4.5. Interactions with other medicinal products and other forms of interaction

Well-established use	Traditional use
	None reported.

4.6. Pregnancy and lactation

Well-established use	Traditional use
	Safety during pregnancy and lactation has not been established. In the absence of sufficient data, the use during pregnancy and lactation is not recommended.

4.7. Effects on ability to drive and use machines

Well-established use	Traditional use
	No studies on the effect on the ability to drive and use machines have been performed.

4.8. Undesirable effects

Well-established use	Traditional use
	None known. If adverse reactions occur, a doctor or a qualified health care practitioner should be consulted.

4.9. Overdose

Well-established use	Traditional use
	No case of overdose has been reported.

5. PHARMACOLOGICAL PROPERTIES

5.1. Pharmacodynamic properties

Well-established use	Traditional use
	Not required as per Article 16c(1)(a)(iii) of Directive 2001/83/EC as amended.

5.2. Pharmacokinetic properties

Well-established use	Traditional use
	Not required as per Article 16c(1)(a)(iii) of Directive 2001/83/EC as amended.

5.3. Preclinical safety data

Well-established use	Traditional use
	Not required as per Article 16c(1)(a)(iii) of Directive 2001/83/EC as amended, unless necessary for the safe use of the product. Tests on reproductive toxicity, genotoxicity and carcinogenicity have not been performed.

6. PHARMACEUTICAL PARTICULARS

Well-established use	Traditional use
	Not applicable.

7. DATE OF COMPILATION/LAST REVISION

7 September 2007